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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,874	01/17/2006	Hiroyuki Shimoji	SAEG124.005APC	3870
20995 7590 06/22/2011 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER ORKIN, ALEXANDER J	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 06/22/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/564,874	<b>Applicant(s)</b> SHIMOJI ET AL.	
	<b>Examiner</b> ALEXANDER ORKIN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2 The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3 Claims 1, 3, 4, 6, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 6,984,242 to Campbell et al. in view of Vivian Hoxbro.

With respect to claim 1, a comparison of the recited process with the prior art process does not serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742 180 U.S.P.Q 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA) 1964. In an ex parte case, product-by-process claims are not construed as being limited to the product

formed by the specific process recited. In re Hirao et al., 535 F2d, 190 U.S.P.Q.

15. Therefore based on the product by process aspect of claim 1 i.e. “the tubular suture reinforcement material *formed by...*”, only a tubular reinforcement structure with the general chain stitch and mechanism of unraveling is needed.

As to claims 1, 6, 10 Igaki discloses a tubular suture reinforcement material and the method of making the material by stacking two sheet-like materials and sewing together both ends using two stitches, and combining the two sheets of materials by sewing two opposite sides to create the tubular structure. However Igaki lacks the two chain stitches and that the thread end passes through loop next to the sewing end which is continuous to the thread end and returned to the sewing end after passing the through the loop next to the sewing end. Instead they disclose a normal stitch. However it is commonly known in the art to use a chain stitch.

Campbell teaches using a chain stitch, where the chain stitches comprises a plurality of loops in which one of the loops passes through an adjacent loop in a direction away from a sewing end, on an open material to be able to releasably close it using one stitch. The stitch has each loop going through the prior loop just like how the chain stitch is defined in this application additionally, the ends of the threads have a loop next to the sewing end that does not pass through the loop next to the sewing end (Fig 3 a,b,). Campbell does teach in figure 4 with reference 54a, a mechanism to temporary secure the thread end by tucking

loops in beneath previous stitches and attaching a clip thereto to temporary secure the stitch (col. 7 ll. 55-64).

Hoxbro teaches a method of stitching where at the end of the stitch, the thread end is thread through a loop that does not go through another loop without forming a knot in order to keep the thread contained and secure but yet still allow it to be easily removable to either release the stitch or continue stitching (see basic square 1). It is known in the art of stitching to bind off the stitch and thread the end of the stitch through a loop at the end that wouldn't be involved with another loop in order to temporarily secure the stitch. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the temporary locking mechanism as taught by Hoxbro with the device of Igaki in order to provide an alternative manner of temporarily securing the stitch to allow for safe packaging of the device by having the device only unravel when wanted.

As to claim 3, with the invention of Igaki ,Campbell, and Hoxbro above, Igaki further discloses the material of the tubular suture reinforcement material being made up from a biodegradable and bioabsorbable knitted, woven, unwoven fabric etc (col. 3, ll. 1-12).

As to claim 4, with the invention of Igaki ,Campbell, and Hoxbro above, Igaki discloses that these materials can be stacked on top of each other with one of them being stretchable in order to make the tubular shape (col. 3, ll. 1-12).

As to claim 11, with the invention of Igaki ,Campbell, and Hoxbro above, Igaki further discloses the automatic suture device comprising a cartridge with

staples and a frame that has a staple receiving slot wherein a tubular suture reinforcement material for an automatic suturing device is fitted to the cartridge and/or frame (Fig. 5).

As to claim 12, with the invention of Igaki ,Campbell, and Hoxbro above, Igaki discloses the method of removing an affected part of a tissue, which could be a lesion from a patient by first sandwiching the tissue in the unwoven fabrics. The tissue is then separated by a cutter. Finally the end of the suture is pulled to separate the section remaining in vivo and the section removed. This leaves part of the material inside the body, while removing some of the material along with the affected part (figure 5-7, col. 3 ll. 33-53).

As to claims 13 and 14, with the invention of Igaki ,Campbell, and Hoxbro above, Igaki discloses using this method in either a soft tissue or in a pulmonary tissue (col. 4, ll. 53-59).

4      Claims 2, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 2,811,299 to Swanson in view of Vivian Hoxbro in further view of U.S. Patent No. 6,063,097 to Oi et al.

As to claim 2, Igaki ,Campbell, and Hoxbro teach the tubular suture reinforcement material above in claim 1, but they lack the tapered end and a knot on the sewing end on a loop to prevent unraveling.

Oi teaches a tubular reinforcement material having the tip part sewed in a tapering fashion (Fig. 7) to prevent turnup of the supporting element (col. 4 ll. 45-48). Oi further teaches a loop on a side of the sewing end is tied to a loop

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immediately before the loop preventing a thread from unraveling (20, figure 8, col. 4 ll. 49-50) so as to prevent separation of the unwoven fabric. It would have been obvious to one of ordinary skill of the art to modify the tip part of the material of Igaki ,Campbell, and Hoxbro to be sewn in a tapered manner as taught by Oi in order to prevent turnup of the supporting element and make a knot at the sewing end in order to prevent separation of the fabric.

5 Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 2,811,299 to Swanson in view of Vivian Hoxbro in further view of U.S. Patent No. 6,273,897 to Dalessandro et al.

As to claim 5, Igaki ,Campbell, and Hoxbro teach the tubular suture reinforcement material above in claim 1 but they lack the projections on the sewing portion of the reinforcement material.

Dalessandro teaches projections on a buttress or a suture reinforcement material. These projections can make it easier to slide the buttress onto the instrument (Fig 12, 13a, 13b, col. 3, ll. 50-2). This same function of using the projections to make it easier to slide a device on the instrument can be used with Igaki ,Campbell, and Hoxbro in loading the suture reinforcement material onto the instrument. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify tubular structure of Igaki with the projection of Dalessandro in order to make it easier to load the tubular suture reinforcement material onto the automatic suturing device.

***Response to Arguments***

6. Applicant's arguments, see pages 5-9, filed 04/08/2011, with respect to the rejections on claims 1-6, 10-14 have been fully considered and are persuasive. The rejections of the claims have been withdrawn.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER ORKIN whose telephone number is (571)270-7412. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Examiner, Art Unit 3773

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Primary Examiner, Art Unit 3773